

- osteogenic protein, dextran, and a matrix, classified in class 514, subclass 49;
- Group III: Claims 1-9, 11-19, 25, 31-33, 35 and 36 drawn to an osteogenic device comprising an osteogenic protein, cellulose, and a matrix, classified in class 514, subclass 47;
- Group IV: Claims 1-9, 11-16, 32, 33, 35 and 36 drawn to an osteogenic device comprising an osteogenic protein, white petrolatum", and a matrix, classified in class 514, subclass 789;
- Group V: Claims 20-24 drawn to an osteogenic device comprising an osteogenic protein, an indeterminate binding agent, and a matrix, indeterminate class and subclass.

The Examiner contends that the inventions encompassed by Groups I-V are patentably distinct from one another and have acquired a separate status in the art. The Examiner contends that the following pairwise combinations of products are independent and distinct, wherein each member of a pair can be manufactured independently of the other and used for independent and distinct purposes: I and each of II-V; II and each of III-V; III and each of IV-V; IV and V. Accordingly, the Examiner states that restriction to one of the five inventions is required.

First, applicants have amended claims 20-24 to depend from claim 1. Accordingly, the Group V claims now fall within the scope of Groups I-IV.

** Applicants believe that the Examiner intended to recite white petrolatum instead of cellulose.

Second, applicants traverse this restriction on the basis of the procedures set forth in the Manual of Patent Examining Procedure ("MPEP").

The MPEP states that if the members of a Markush group are sufficiently few in number that a search and examination of the entire claim can be made without serious burden, "the examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions" (emphasis added). MPEP §803.02. Applicants respectfully request that the Examiner reconsider the restriction requirement in view of this MPEP procedural rule.

Applicants respectfully request that Groups I-IV be examined together. Each of these Groups recites an osteogenic device comprising an osteogenic protein, a binding agent and a matrix. The different binding agents mannitol, dextran, cellulose, white petrolatum, and derivatives thereof, in claims 1-9, 11-25, 31-33, 35 and 36 are recited as members of a Markush group. This Markush group is made up of only four members. Four members is "sufficiently few" and accordingly, the Examiner must examine all four members together.

If the Examiner does not agree with applicants' proposal to rejoin Groups I-V, applicants provisionally elect with traverse the claims of Group III (claims 1-9, 11-19, 25, 31-33, 35 and 36) for initial substantive examination. 37 C.F.R. § 1.143. This election is made expressly without waiver of applicants' rights to continue to prosecute and to obtain claims to the non-elected and/or canceled subject matter either in this application or in other applications claiming priority herefrom.

ELECTION REQUIREMENT

The Examiner states that the claims are directed to the following patentably distinct species:

(a) a single osteogenic protein or (b) two different osteogenic proteins. The Examiner has required that applicants pursuant to 35 U.S.C. § 121 elect either a single species of osteogenic protein from claim 2 for the single osteogenic protein or two different osteogenic proteins from claim 2 for the two different osteogenic proteins. The Examiner has also required that applicants identify all claims that read on the elected species.

Applicants elect the single osteogenic species OP-1. Claims 1-9, 11-25, 31-33, 35 and 36 read on the elected species OP-1.

The Examiner also states that the claims are directed to the following patentably distinct species: (a) a single matrix species or (b) a combination of two different matrix species. The Examiner has required that applicants, pursuant to 35 U.S.C. § 121 elect either a single matrix species from claim 7 for the single matrix species or two different matrix species from claim 7 for the two different matrix species. The Examiner has also required that applicants identify all claims that read on the elected species.

Applicants elect the single matrix species collagen. Claims 1-9, 11-25, 31-33, 35 and 36 read on the elected species collagen.

The Examiner further states that the claims are directed to the following patentably distinct species: (a) the species cellulose in claim 12 or (b) at least two

binding agents. The Examiner has also required that applicants identify all claims that read on the elected species.

Applicants elect the single cellulose species carboxymethylcellulose. Claims 1-9, 11-25, 31-33, 35 and 36 read on the elected species carboxymethylcellulose.

CONCLUSION

In view of the above, applicants request that the Examiner examine the pending claims in this application. Applicants request favorable consideration and early allowance of the pending claims.

Respectfully submitted,

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